

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/25/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12511050]
2.	Birth Date:	(b) (6)/1964
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN
6.	Racial Designation:	

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/25/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Form Comments](#)

[eCRF Audit Trail History](#)

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	
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**Exclusion Criteria Met**

2.a	Description of Exclusion Criterion Met	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/25/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post menopausal]
	Start Date:	Oct/17/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tubal Ligation]
	Start Date:	Feb/27/1992
	Ongoing:	NO End Date: Feb/27/1992
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[R Ankle pain]
	Start Date:	Mar/UNK/2020
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depression]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1 f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Hepatitis C]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety Disorder]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1 h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Smoker]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bipolar II Disorder]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cyst of Skin Lower Back]
	Start Date:	UNK/UNK/1999
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

1 k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Major Depressive Disorder]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Prolapsed Lumbar Intervertebral Disc]
	Start Date:	UNK/UNK/1997
	Ongoing:	YES
1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Back Pain]
	Start Date:	UNK/UNK/1997
	Ongoing:	YES
1 n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[History of Drug Abuse]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[History of Adenomatous Polyp of Colon]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/25/2020
2.	Weight:	[232.0]
3.	Unit:	LB
4.	Height:	[70.0]
5.	Unit:	in
6.	Body Mass Index:	[33.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Done _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Done _____	<a href="#">Comments</a>
3.	Collection Date:	Not Done _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Done _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Done _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Not Done _____ Choriogonadotropin Beta_PX113	
	Result:	Not Done _____	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>

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<b>Header Text:</b> c4591001	<b>Form:</b> RANDOMIZATION
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:03	<b>Site Name:</b> (1251) Achieve Clinical Research
<b>Site No:</b> 1251	<b>Subject Initials:</b> ---
<b>Subject No:</b> 12511050	<b>Generated Time (GMT):</b> 29-Mar-2021 18:51
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Aug/25/2020
2.	Randomization Number:	[239433]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYNTK]
5.b	Sample ID	[BPYNTL]
5.c	Sample ID	[BPYNTM]
5.d	Sample ID	[BNWBHM]
5.e	Sample ID	[BNWBHN]

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYNFB]
-----	-----------	----------

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/25/2020 09:40
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/6/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/6/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[99.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/6/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR90M7]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Form Comments](#)  
[eCRF Audit Trail History](#)

Vaccination			
1.	Was there a temporary delay of vaccination?	Not Applicable _____	<a href="#">Comments</a>
2.	Treatment Name	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Applicable _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Applicable _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Applicable _____	<a href="#">Comments</a>
6.	Body Side:	Not Applicable _____	<a href="#">Comments</a>
7.	Route:	Not Applicable _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Applicable _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Applicable _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Applicable _____	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/3/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Blood/Swab samples are collected/recorded in Convalescent Visit]

**Aliquot**

Please enter barcode for each aliquot.

<del>5.a</del>	Sample ID	[ ]
<del>5.b</del>	Sample ID	[ ]
<del>5.c</del>	Sample ID	[ ]
<del>5.d</del>	Sample ID	[ ]
<del>5.e</del>	Sample ID	[ ]

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**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020      **Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/16/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

**Signs and Symptoms**

1.	Date of Assessment:	Sep/16/2020
2.	Date of First Symptom Started:	Sep/16/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Sep/18/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	YES
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

5.a	Symptoms - Other Text:	[Nasal Drainage]
-----	------------------------	------------------

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Sep/16/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Sep/16/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[NALT unknown]

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020      **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[She had a Covid Test at her Physician's Office]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject had Covid Test in her Physician's Office]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**eCRF Audit Trail History****Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
----	-------------------------------------	-----

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Respiratory Treatment**

1.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
3.	Treatment:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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[eCRF Audit Trail History](#)

**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Sep/16/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.b	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.c	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Sep/16/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.d	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	
5.e	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Sep/16/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5 f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Sep/16/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.b	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.c	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.d	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Platelets_PX5	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ]		
	High [ ]		
	Unit		
5.e	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ]		
	High [ ]		
	Unit		

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Sep/16/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.h	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.i	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Basophils_PX610	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.j	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Applicable _____	<a href="#">Comments</a>	
LNMT	Not Applicable _____	<a href="#">Comments</a>	
	Low [ ]		
	High [ ]		
	Unit		

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Sep/16/2020

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Vital Signs**

1.	Date:	Not Applicable _____ //	<a href="#">Comments</a>
----	-------	-------------------------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Sep/16/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Imaging**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Applicable _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Applicable _____	<a href="#">Comments</a>
4.	Assessment:	Not Applicable _____	<a href="#">Comments</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
on Nov/03/2020

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Date of Visit**

1.	Date of Visit	Nov/3/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Nov/03/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2K78]
5.b	Sample ID	[BR2K79]
5.c	Sample ID	[BR2K7B]
5.d	Sample ID	[BSHYZY]
5.e	Sample ID	[BSHYZZ]

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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Unplanned Assessments**

1.	Assessments	
----	-------------	--

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Nov/3/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	PHYSICIAN DECISION
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----



**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	exacerbation of hypertension	Sep/4/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[exacerbation of hypertension]
4.	Start Date Time:	Sep/4/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED  If Not Related to study treatment(s), this event is due to: OTHER  If Other, specify: [environmental factors, psychiatric factors]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020361606]

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Medication Error**

1.	Category:	Not Applicable _____	<a href="#">Comments</a>
2.	Medication Error (Type of Medication Error):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Is the medication error still ongoing?	Not Applicable _____	<a href="#">Comments</a>
5.	Latest Action Taken with Study Treatment:	Not Applicable _____	<a href="#">Comments</a>
6.	Was a Concomitant Medication given?	Not Applicable _____	<a href="#">Comments</a>
7.	Was a Non-Drug Treatment given?	Not Applicable _____	<a href="#">Comments</a>
8.	Did the Medication Error cause the subject to be discontinued from the study?	Not Applicable _____	<a href="#">Comments</a>
9.	Was this medication error associated with any adverse events?	Not Applicable _____	<a href="#">Comments</a>
10.	Serious Adverse Event Number: For Pfizer Use Only	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Date:	Not Applicable _____ //	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Dose:	Not Applicable _____ [ ]	<a href="#">Comments</a>
6.	Dose Unit:	Not Applicable _____	<a href="#">Comments</a>
7.	Dose Frequency:	Not Applicable _____	<a href="#">Comments</a>
8.	Route:	Not Applicable _____	<a href="#">Comments</a>
9.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
10.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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[Form Comments](#)

[eCRF Audit Trail History](#)

**Radiation Treatment**

1.	Category:	Not Applicable _____	<a href="#">Comments</a>
2.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

#	Transfusion Type	Date of Transfusion	Form Instance
1.	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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1.	Transfusion Type:	Not Applicable _____	<a href="#">Comments</a>
2.	Date of Transfusion:	Not Applicable _____ //	<a href="#">Comments</a>

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Vital Signs**

1.	Date:	//
----	-------	----

**Vital Signs Details**

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Not Started

**Site No:** 1251 **Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled    **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
----	--------------	--

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled    **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled    **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Treatment Unblinded**

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Death Details**

1.	Date of Collection / Notification of Death:	//
----	---	----

**Cause of Death**

2.	Cause of Death Status:	
	Cause of Death:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/3/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Hayes Williams	Approved	Mar-10-2021 15:18:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, HayesWilliams, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-03-2020 14:24:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	subject does not meet inclusion 3 based on new information withheld by subject at V1.
Form	Aug-25-2020 10:26:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done
3	Aug-25-2020 10:29:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6.a	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done
6.a	Aug-25-2020 10:29:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6.a	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done
6.a	Aug-25-2020 10:29:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6.a	Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	not done Not Done
6.a	Aug-25-2020 10:29:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6.a	Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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Item	Date	User	Comment
6.a	Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	n/a <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	SUBJECT WILL NOT RECEIVE 2ND VACCINATION DUE TO CHRONIC HEPATITIS C-PER INVESTIGATOR <hr/> Not Applicable
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**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

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**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	SUBJECT WILL NOT RECEIVE 2ND VACCINATION DUE TO CHRONIC HEPATITIS C-PER INVESTIGATOR <hr/> Not Applicable

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Item	Date	User	Comment
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**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

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**Form Status:** Data Complete, Locked, Frozen, Verified

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**Subject Initials:** ---

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Item	Date	User	Comment
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Item	Date	User	Comment
9	Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	SUBJECT WILL NOT RECEIVE 2ND VACCINATION DUE TO CHRONIC HEPATITIS C-PER INVESTIGATOR <hr/> Not Applicable

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
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**Site No:** 1251

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**Form:** VACCINATION - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
11	Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	SUBJECT WILL NOT RECEIVE 2ND VACCINATION DUE TO CHRONIC HEPATITIS C-PER INVESTIGATOR <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-04-2020 08:29:41 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

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**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

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**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

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**Generated By:** (b) (4)

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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

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**Generated By:** (b) (4)

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Item	Date	User	Comment
Form	Nov-04-2020 08:33:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

**Header Text:** c4591001

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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
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**Form Version:** 21-Aug-2020 02:49

**Site No:** 1251

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**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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**Site Name:** (1251) Achieve Clinical Research

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Item	Date	User	Comment
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**Header Text:** c4591001

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			Not Applicable

**Header Text:** c4591001

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-04-2020 08:35:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Nov-04-2020 08:35:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments

**Form Version:** 21-Aug-2020 02:51

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** OXYGENATION PARAMETERS - Comments

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Nov-04-2020 08:35:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** OXYGENATION PARAMETERS - Comments

**Form Version:** 06-Jul-2020 21:52

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**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Nov-04-2020 08:35:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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**Form Version:** 06-Jul-2020 21:55

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**Generated By:** (b) (4)

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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
1	Nov-04-2020 08:36:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

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Item	Date	User	Comment
2	Nov-04-2020 08:36:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
4	Nov-04-2020 08:36:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	NA Not Applicable

**Header Text:** c4591001

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**Form Version:** 17-Jul-2020 21:54

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**Form Status:** Data Complete, Locked, Frozen, Verified

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

**Header Text:** c4591001

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**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

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**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

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Item	Date	User	Comment
3	Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

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Item	Date	User	Comment
4	Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
9	Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

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Item	Date	User	Comment
10	Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

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**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

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**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

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Item	Date	User	Comment
Form	Sep-23-2020 09:33:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
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**Header Text:** c4591001

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**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -  
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
7	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

**Header Text:** c4591001

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**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
8	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
9	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

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**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
10	Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

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**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
4	Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
5	Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Sep-23-2020 09:34:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
1	Sep-23-2020 09:34:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Item	Date	User	Comment
2	Sep-23-2020 09:34:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Hayes Williams	Approved	Mar-10-2021 15:18:30 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, HayesWilliams, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-26-2021 11:28:48 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Hayes Williams	Approved	Nov-09-2020 09:04:47 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, HayesWilliams, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-25-2020 10:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

*2. Select appropriate response - What cohort does the subject belong to?*

Date	Location	User	Value	Reason
Aug-25-2020 10:24:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-25-2020 10:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/25/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-23-2020 15:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	I saw update on the AE log. Thank you.
Sep-21-2020 18:45:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Subject has a Med hx of Hypertension from 2010. In the case of decompensation of HTN, the event term could be consistent with an hypertensive crisis (Urgency or emergency). Please consider revision and update accordingly. Thank you.
Sep-21-2020 09:23:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Hypertension is serious
Sep-18-2020 05:34:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020361606 increased hypertension(onset date:04Sep2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Aug-25-2020 10:24:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12511050	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:24:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) /1964	Enrollment Entry

**3. Sex:**

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Aug-25-2020 10:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-25-2020 10:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-25-2020 10:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLACK OR AFRICAN AMERICAN	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-06-2020 05:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 16:08:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated. Subject history of Hep C was unknown and not reported by Subject.
Nov-05-2020 04:53:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: the comment on the vax CRF indicates subject has chronic hep C. Please update inc/ex CRF as appropriate. The page has been unfrozen now. Many thanks
Nov-03-2020 14:25:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Left comment about failed criteria. Please unfreeze page.
Nov-02-2020 03:10:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery: the comment on the vax CRF indicates subject has chronic hep C. Please update inc/ex CRF as appropriate.
Oct-30-2020 12:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	ClinQuery: the comment on the vax CRF indicates subject has chronic hep C. Please update inc/ex CRF as appropriate.
Oct-29-2020 13:59:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-29-2020 10:07:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	ClinQuery - please could you recheck - it does not look frozen to me. many thanks

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Oct-29-2020 09:53:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	inc/ex is frozen please unfreeze
Oct-29-2020 05:42:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: the comment on the vax CRF indicates subject has chronic hep C. Please update inc/ex CRF as appropriate.
Aug-25-2020 10:25:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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2.a

Date	Location	User	Value	Reason
Nov-05-2020 16:04:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Criteria</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.a Description of Exclusion Criterion Met

Date	Location	User	Value	Reason
Nov-05-2020 16:04:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-25-2020 10:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-25-2020 10:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-25-2020 10:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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*I.a*

Date	Location	User	Value	Reason
Aug-25-2020 10:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Post menopausal <b>Start Date:</b> Oct/17/2018 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-25-2020 10:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

*I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Oct-29-2020 10:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-29-2020 09:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated
Oct-29-2020 05:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: the comment on the vax CRF indicates subject has chronic hep C. Please update medical history as appropriate.
Aug-25-2020 10:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Post menopausal	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Aug-25-2020 10:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/17/2018	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 10:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Aug-25-2020 10:28:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Hypertension <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:28:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 10:28:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:28:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 10:28:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

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Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

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Site Name: (1251) Achieve Clinical Research

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I.c

Date	Location	User	Value	Reason
Sep-21-2020 09:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Tubal Ligation <b>Start Date:</b> Feb/27/1992 <b>Ongoing:</b> NO End Date: Feb/27/1992	Transcription Error
Sep-21-2020 09:46:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Tubal Ligation <b>Start Date:</b> Feb/27/1992 <b>Ongoing:</b> NO End Date: Feb/2/1992	Transcription Error
Aug-25-2020 10:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Tubal Ligation <b>Start Date:</b> Feb/2/1992 <b>Ongoing:</b> NO End Date: Feb/2/1992	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

**I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 10:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Tubal Ligation	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-21-2020 09:46:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/27/1992	Transcription Error
Aug-25-2020 10:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/2/1992	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-21-2020 09:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-21-2020 09:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  Feb/27/1992	Transcription Error
Sep-21-2020 09:46:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Term Tubal Ligation End Date is prior to Start Date.
Aug-25-2020 10:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  Feb/2/1992	Initial Entry

**I.d**

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Aug-25-2020 10:43:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> R Ankle pain <b>Start Date:</b> Mar/UNK/2020 <b>Ongoing:</b> YES	Initial Entry

**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:43:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 10:43:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> R Ankle pain	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:43:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/UNK/2020	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 10:43:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Sep-16-2020 15:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> depression	Initial Entry

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Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

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			<b>Start Date:</b>	UNK/UNK/2018	
			<b>Ongoing:</b>	YES	

*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Sep-16-2020 15:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

*I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Sep-16-2020 15:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> depression	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Sep-16-2020 15:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Sep-16-2020 15:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Oct-29-2020 09:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> Chronic Hepatitis C <b>Start Date:</b> UNK/UNK/2009 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

*I.f Line/MH Number:*

Date	Location	User	Value	Reason
Oct-29-2020 09:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

*I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Oct-29-2020 09:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Chronic Hepatitis C	Initial Entry

*I.f Start Date:*

Date	Location	User	Value	Reason
Oct-29-2020 09:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2009	Initial Entry

*I.f Ongoing:*

Date	Location	User	Value	Reason
Oct-29-2020 09:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.g*

Date	Location	User	Value	Reason
Feb-26-2021 11:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> Anxiety Disorder <b>Start Date:</b> UNK/UNK/2017 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*I.g Line/MH Number:*

Date	Location	User	Value	Reason
Feb-26-2021 11:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

*I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Feb-26-2021 11:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Anxiety Disorder	Initial Entry

*I.g Start Date:*

Date	Location	User	Value	Reason
Feb-26-2021 11:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2017	Initial Entry

*I.g Ongoing:*

Date	Location	User	Value	Reason
Feb-26-2021 11:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

*I.h*

Date	Location	User	Value	Reason
Feb-26-2021 11:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 8 Medical History Term: Smoker Start Date: UNK/UNK/19 89 Ongoing: YES	Initial Entry

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Subject No: 12511050

Generated By: (b) (4)

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Subject Initials: ---

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**I.h Line/MH Number:**

Date	Location	User	Value	Reason
Feb-26-2021 11:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 8	Initial Entry

**I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Feb-26-2021 11:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Smoker	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Feb-26-2021 11:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1989	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Feb-26-2021 11:29:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Feb-26-2021 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> Bipolar II Disorder <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

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Subject No: 12511050

Generated By: (b) (4)

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***I.i Line/MH Number:***

Date	Location	User	Value	Reason
Feb-26-2021 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

***I.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Feb-26-2021 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bipolar II Disorder	Initial Entry

***I.i Start Date:***

Date	Location	User	Value	Reason
Feb-26-2021 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

***I.i Ongoing:***

Date	Location	User	Value	Reason
Feb-26-2021 11:30:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.j***

Date	Location	User	Value	Reason
Feb-26-2021 11:31:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 10 <b>Medical History:</b> Cyst of Skin Lower Back <b>Term:</b> r Back <b>Start Date:</b> UNK/UNK/1999 <b>Ongoing:</b> YES	Initial Entry

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Subject No: 12511050

Generated By: (b) (4)

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Subject Initials: ---

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**I.j Line/MH Number:**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

**I.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cyst of Skin Lower Back	Initial Entry

**I.j Start Date:**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1999	Initial Entry

**I.j Ongoing:**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.k**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 11 <b>Medical History Term:</b> Major Depressive Disorder <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> YES	Initial Entry

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Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

**I.k Line/MH Number:**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

**I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Major Depressive Disorder	Initial Entry

**I.k Start Date:**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

**I.k Ongoing:**

Date	Location	User	Value	Reason
Feb-26-2021 11:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.l**

Date	Location	User	Value	Reason
Feb-26-2021 11:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 12 <b>Medical History Term:</b> Prolapsed Lumbar Intervertebral Disc <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

**I.I Line/MH Number:**

Date	Location	User	Value	Reason
Feb-26-2021 11:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

**I.I Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Feb-26-2021 11:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Prolapsed Lumbar Intervertebral Disc	Initial Entry

**I.I Start Date:**

Date	Location	User	Value	Reason
Feb-26-2021 11:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1997	Initial Entry

**I.I Ongoing:**

Date	Location	User	Value	Reason
Feb-26-2021 11:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.m**

Date	Location	User	Value	Reason
Feb-26-2021 11:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 13 <b>Medical History Term:</b> Chronic Back Pain <b>Start Date:</b> UNK/UNK/1997 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

***I.m Line/MH Number:***

Date	Location	User	Value	Reason
Feb-26-2021 11:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

***I.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Feb-26-2021 11:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Chronic Back Pain	Initial Entry

***I.m Start Date:***

Date	Location	User	Value	Reason
Feb-26-2021 11:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1997	Initial Entry

***I.m Ongoing:***

Date	Location	User	Value	Reason
Feb-26-2021 11:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.n***

Date	Location	User	Value	Reason
Feb-26-2021 11:34:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number 14 : Medical History T History of Drug Abuse erm: buse Start Date: UNK/UNK/2002 Ongoing: YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

***I.n Line/MH Number:***

Date	Location	User	Value	Reason
Feb-26-2021 11:34:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

***I.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Feb-26-2021 11:34:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> History of Drug Abuse	Initial Entry

***I.n Start Date:***

Date	Location	User	Value	Reason
Feb-26-2021 11:34:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2002	Initial Entry

***I.n Ongoing:***

Date	Location	User	Value	Reason
Feb-26-2021 11:34:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.o***

Date	Location	User	Value	Reason
Feb-26-2021 11:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 15 <b>Medical History Term:</b> History of Adenomatous Polyp of Colon <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

***I.o Line/MH Number:***

Date	Location	User	Value	Reason
Feb-26-2021 11:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

***I.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Feb-26-2021 11:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> History of Adenomatous Polyp of Colon	Initial Entry

***I.o Start Date:***

Date	Location	User	Value	Reason
Feb-26-2021 11:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***I.o Ongoing:***

Date	Location	User	Value	Reason
Feb-26-2021 11:35:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.p***

Date	Location	User	Value	Reason
Feb-26-2021 11:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 16 <b>Medical History Term:</b> Insomnia <b>Start Date:</b> UNK/UNK/2009 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

*I.p Line/MH Number:*

Date	Location	User	Value	Reason
Feb-26-2021 11:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 16	Initial Entry

*I.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Feb-26-2021 11:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Insomnia	Initial Entry

*I.p Start Date:*

Date	Location	User	Value	Reason
Feb-26-2021 11:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2009	Initial Entry

*I.p Ongoing:*

Date	Location	User	Value	Reason
Feb-26-2021 11:35:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-25-2020 10:29:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Transcription Error
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Vital signs Date 24/Aug/2020 is not same as Date of Visit 25/Aug/2020. Please review and update as appropriate or clarify.
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/24/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 232.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 70.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
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090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry
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6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 33.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier:: 1 Temperature: 98.5 Temperature Unit: F Temperature Location: ORAL CAVITY n:: Y	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Aug-25-2020 10:29:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-25-2020 10:30:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done Test::: Not Done	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Aug-25-2020 10:29:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-25-2020 10:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-25-2020 10:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 239433	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 10:31:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-25-2020 10:31:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-25-2020 18:57:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_BEETRK001_04
Aug-25-2020 13:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Aug-25-2020 13:56:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/25/2020	Transcription Error
Aug-25-2020 13:00:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW4352182;Date of Collection is earlier or more than 1 day after Date of Visit. Please clarify or correct.
Aug-25-2020 10:32:14	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-06:00) Central Time (US & Canada)				
Aug-25-2020 10:31:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ca ndidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 10:31:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Co llection:  Aug/24/2 020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Oct-22-2020 15:09:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (b) (4)	Query 1: Closed	Query not needed per SPA guidance.
Oct-20-2020 12:21:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Aug-25-2020 10:32:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-25-2020 10:32:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPYNTK	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
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090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Aug-25-2020 10:32:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYNTK	Initial Entry
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**5.b**

Date	Location	User	Value	Reason
Aug-25-2020 10:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPYNTL	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 10:32:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYNTL	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-25-2020 10:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPYNTM	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 10:32:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYNTM	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-25-2020 10:33:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BNWBHM	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 10:33:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWBHM	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.e

Date	Location	User	Value	Reason
Aug-25-2020 10:33:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWBHN	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 10:33:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWBHN	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 10:33:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-25-2020 10:33:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-25-2020 10:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 10:33:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 10:33:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/25/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-25-2020 10:33:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPYNFB	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-25-2020 10:33:51	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-06:00) Central Time  
(US & Canada)

(b) (4), (b) (6)

BPYNFB

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/25/2020 09:40	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

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090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Aug-25-2020 10:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-25-2020 10:34:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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***I. Date of Visit***

Date	Location	User	Value	Reason
Oct-14-2020 00:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per site confirmation - updated PD tracker
Oct-13-2020 09:23:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	confirming visit is out of window
Oct-12-2020 11:16:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Opened	PDQ: Date of visit at V2_VAX2_L is out of window for 19 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Oct-09-2020 08:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Initial Entry
Oct-09-2020 08:58:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry
Oct-06-2020 04:38:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Canditate	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.
Oct-05-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject has not been

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

10:28:19 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	swered	seen as a V2
Sep-26-2020 12:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date:**

Date	Location	User	Value	Reason
Oct-09-2020 08:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-09-2020 08:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 99.1 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-09-2020 08:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-09-2020 08:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-09-2020 08:58:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-09-2020 08:58:43 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

(US & Canada)				
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**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1251**Subject No:** 12511050**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1251) Achieve Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:49

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b>	Not Applicable
			<b>Not Done::</b>	Not Applicable

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a Not Done:**

Date	Location	User	Value	Reason
Oct-09-2020 09:00:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-09-2020 09:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-09-2020 09:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-09-2020 09:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-09-2020 09:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 09:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/6/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-09-2020 09:07:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR90M7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-09-2020 09:07:05	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-06:00) Central Time  
(US & Canada)

(b) (4), (b)  
(6) BR90M7



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-06-2020 17:06:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 08:33:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	N/A
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-06-2020 01:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Thanks for the response. Please review and update the form level comment as Not Applicable on this form. Else, clarify.
Nov-05-2020 12:13:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT NOT TO RECEIVE VACCINATION PER PI DUE TO CHRONIC HEPATITIS C. PLEASE READ PROGRESS NOTE IN FLORENCE.
Nov-04-2020 23:24:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: As subject is not going to receive VCC2 per comment provided then please consider to update this form as Not applicable or else clarify. Thank you.

**2. Treatment Name**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Formulation:**

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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Nov-06-2020 08:05:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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***I. Date of Visit***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-05-2020 23:56:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Closed as per site response.
Nov-05-2020 08:17:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	confirming both visits were on the same day
Nov-05-2020 01:26:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW5285125;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_A1. Please review for duplication and update as appropriate.
Nov-04-2020 08:05:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Nov/3/ 2020	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 08:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-04-2020 08:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-04-2020 11:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Closed	Close Auto Query
Nov-04-2020 11:52:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Nov-04-2020 11:52:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Closed	Close Auto Query
Nov-04-2020 11:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Nov-04-2020 11:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Nov-04-2020 11:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Nov-04-2020 11:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-04-2020 11:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Nov-04-2020 11:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-04-2020 11:50:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-04-2020 11:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Sample Collected?" is No, but Barcodes are present on the page.
Nov-04-2020 11:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Nov-04-2020 11:49:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Changed Information
Nov-04-2020 08:08:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 08:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 08:06:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/3/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-04-2020 11:50:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood/Swab samples are collected/rec orded in Convalescent Visit	Initial Entry
Nov-04-2020 08:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-04-2020 08:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-04-2020 08:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Nov-04-2020 08:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHYZZ	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-06-2020 08:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Nov-04-2020 08:08:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR2K78	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-06-2020 08:27:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error <b>(DELETED)</b>

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-04-2020 11:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-04-2020 08:08:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR2K78	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-06-2020 08:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Nov-04-2020 08:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR2K79	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-06-2020 08:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:51:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-04-2020 08:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR2K79	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-06-2020 08:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Nov-04-2020 08:09:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR2K7B	Initial Entry
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**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-06-2020 08:27:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-04-2020 08:09:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR2K7B	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Nov-06-2020 08:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:52:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Nov-04-2020 08:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSHYZY	Initial Entry

**5.d Sample ID**

Date	Location	User	Value	Reason
Nov-06-2020 08:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:52:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-04-2020 08:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHYZY	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.e

Date	Location	User	Value	Reason
Nov-06-2020 08:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Nov-04-2020 08:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BSHYZZ</b>	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 08:28:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error <b>(DELETED)</b>
Nov-04-2020 11:52:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-04-2020 08:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHYZZ	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-05-2020 23:45:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Nov-05-2020 16:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Nasal swab was not collected.
Nov-05-2020 03:34:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ : Details of Sample ID and collection date for either Nasal Swab Self or Nasal Swab expected to be completed. Please check and update else clarify.
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-04-2020 08:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-04-2020 08:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-04-2020 08:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**3. COVID-19 Illness Visit:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Nov-04-2020 08:19:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Sep/18/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.b

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.d

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P YES resent:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.f

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom P resent:</b> NO	Initial Entry

**4.f Symptoms:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom P resent:</b> NO	Initial Entry

**4.g Symptoms:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THRO AT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1251**Subject No:** 12511050**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1251) Achieve Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51**4.h**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History  
**Form Version:** 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified  
**Site No:** 1251 **Site Name:** (1251) Achieve Clinical Research  
**Subject No:** 12511050 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Nov-04-2020 08:21:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Nasal Drainage	Initial Entry
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**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Nov-04-2020 08:21:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nasal Drainage	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

**Form Version:** 06-Jul-2020 21:54

**Form Status:**

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-06-2020 01:38:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Nov-05-2020 08:17:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-05-2020 08:17:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT unknown	Changed Information
Nov-05-2020 05:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	If trade name is not known, As per CCG, NALT Unknown should be updated in specified field, thank you. (b) (4)
Nov-04-2020 08:24:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unsheduled Visit on Sep/16/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 08:44:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-04-2020 08:44:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-04-2020 08:44:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-04-2020 08:44:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> She had a Covid Test at her Physician's Office	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 08:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-04-2020 08:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-04-2020 08:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-04-2020 08:45:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject had Covid Test in her Physician's Office	Changed Information
Nov-04-2020 08:37:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject had Covid test somewhere else	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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*I.a*

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: SPECIAL IST Occurrence of Visits or C ontacts: NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: EMERGENC Y ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

***I.d***

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***I.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.e***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***I.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***I.f***

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHE R <b>Occurrence of Visits or Cont acts:</b> NO	Initial Entry
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***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Nov-04-2020 08:29:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Nov-04-2020 08:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Nov-04-2020 08:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Nov-04-2020 08:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Nov-04-2020 08:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-04-2020 08:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 08:29:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-04-2020 08:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Nov-04-2020 08:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-04-2020 08:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-04-2020 08:33:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Nov-04-2020 08:33:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Nov-04-2020 08:33:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-04-2020 08:33:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifi Not Applica	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)	(b) (4), (b) (6)	<b>fier:</b> ble <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.d

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifi Not Applica	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)		(b) (4), (b) (6)	<b>fier:</b> ble <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.g

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifi</b> Not Applica	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)	(b) (4), (b) (6)	<b>fier:</b> ble <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.d

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifi</b> Not Applica	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)		(b) (4), (b) (6)	<b>fier:</b> ble <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

5.g

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifi</b> Not Applica	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

(US & Canada)	(b) (4), (b) (6)	<b>fier:</b>	ble
		<b>Test::</b>	Not Applica ble
		<b>Result::</b>	Not Applica ble
		<b>Not Done::</b>	Not Applica ble
		<b>Lab Normal Range:</b>	Not Applica ble

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Result::</b>	Not Applicable
			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-04-2020 08:34:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Systolic::</b> Not Applicable <b>Diastolic::</b> Not Applicable <b>Respiratory Rate in respirations/minute:</b> Not Applicable <b>Heart Rate in beats/minute:</b> Not Applicable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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*1. Date:*

Date	Location	User	Value	Reason
Nov-04-2020 08:35:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Nov-04-2020 08:35:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Oxygen Saturation:</b> Not Applicable	Initial Entry

*2.a Record Identifier:*

Date	Location	User	Value	Reason
Nov-04-2020 08:35:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

*2.a SPO2 Pulse Oximetry %*

Date	Location	User	Value	Reason
Nov-04-2020 08:35:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Nov-04-2020 08:35:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-04-2020 08:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:30 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(US & Canada)

(b) (4), (b) (6)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/16/2020 Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-04-2020 08:36:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Nov/03/2020 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-06-2020 23:35:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Nov-06-2020 09:00:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	Immunogenicity form is complete.
Nov-06-2020 08:38:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Nov-05-2020 12:15:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	CONFIRMING VISITS ON THE SAME DAY.
Nov-05-2020 05:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	DM: Kindly review and complete 'Immunogenicity form' at this visit. Thank you.
Nov-05-2020 01:26:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW5285124;The Date of Visit at Visit COVID_A1 is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate.
Nov-04-2020 08:45:52	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b>	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History on Nov/03/2020

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-06:00) Central Time (US & Canada)				i Nov/3 /2020
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**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Nov-04-2020 08:45:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COVID_A1	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Nov/03/2020 Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1251**Site Name:** (1251) Achieve Clinical Research**Subject No:** 12511050**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-06-2020 08:24:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-06-2020 08:24:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-06-2020 08:24:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/3/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-06-2020 08:24:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR2K78	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-06-2020 08:24:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR2K78	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-06-2020 08:24:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR2K79	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Nov/03/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.b Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 08:24:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR2K79	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-06-2020 08:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR2K7B	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 08:24:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR2K7B	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-06-2020 08:26:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSHYZY	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 08:26:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHYZY	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-06-2020 08:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSHYZZ	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Nov/03/2020 Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

*5.e Sample ID*

Date	Location	User	Value	Reason
Nov-06-2020 08:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHYZZ	Initial Entry

**Header Text:** c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 15-Sep-2020 21:55**Site No:** 1251**Subject No:** 12511050**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1251) Achieve Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-04-2020 08:18:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry
Nov-04-2020 08:17:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-02-2020 04:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-30-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-30-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/6/2020	Transcription Error
Oct-29-2020 05:44:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: please clarify if the subject was withdrawn from treatment and if appropriate please update the EOT CRF.

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-04-2020 08:18:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry
Nov-04-2020 08:17:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Oct-30-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Transcription Error

**3. Status:**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Nov-07-2020 02:50:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 08:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-06-2020 08:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is PHYSICIAN DECISION but "Specify Status" is Provided.
Nov-06-2020 08:58:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PHYSICIAN DECISION	Changed Information
Nov-06-2020 07:55:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been answered on 11-5-20
Nov-06-2020 01:26:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Per response, 'subject is not received Vaccination 2.' However, Status is recorded as COMPLETED on this form. Please review and update. Else, clarify.
Nov-05-2020 12:14:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT WILL NOT RECEIVE 2ND VACCINATION PER PI DUE TO CHRONIC HEPATITIS C. PLEASE READ PROGRESS NOTE IN FLORENCE
Nov-05-2020 08:48:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Subject has not received vaccination 2, but status of end of treatment disposition is entered as COMPLETED. Please verify and update accordingly, else clarify. Thank you.

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Nov-04-2020 08:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Changed Information
Oct-30-2020 16:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PHYSICIAN DECISION	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Nov-06-2020 08:59:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Nov-06-2020 08:58:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The subject was withdrawn from treat ment per PI decision.	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-04-2020 08:06:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Response satisfies query
Nov-04-2020 08:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Updating report
Oct-28-2020 15:23:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	If test was NOT performed or NOT available, please add this information providing FU report as well so it is reflected in the SAE case narrative. Thank you.
Oct-28-2020 12:32:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	not performed
Oct-27-2020 10:35:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Reissued:Opened	If test was performed = YES, please provide/record results in narrative providing FU report. If test was NOT performed or NOT available, please add this information as well so it is reflected in

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

				the SAE case narrative.
Oct-27-2020 10:30:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	no additional information to report at this time
Oct-21-2020 10:13:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed (yes/no) and if yes, the results. Thank you.
Oct-17-2020 08:01:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-16-2020 10:01:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-16-2020 10:01:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> exacerbation of hypertension	Changed Information
Oct-11-2020 08:03:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2020361606,the term was updated to 'hypertensive urgency' in AE CRF while retained as 'exacerbation of hypertension' in Safety database. Please confirm correct term.If safety update is required, please submit a follow-up form.
Oct-08-2020 12:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Oct-08-2020 10:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-08-2020 10:39:27 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypertensive urgency	Changed Information

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)				
Oct-07-2020 15:23:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for your response. If this is an Hypertensive urgency, please update term accordingly.
Oct-07-2020 12:03:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	urgency
Sep-28-2020 13:55:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	In the case of decompensation of HTN, the event preferred term could be consistent with an hypertensive Urgency or emergency. Please consider revision and update accordingly. Thank you.
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exacerbation of hypertension	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/4/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

7. Is the adverse event serious?				
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1251) Achieve Clinical Research

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Generated Time (GMT): 29-Mar-2021 18:51

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-24-2020 04:21:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-24-2020 02:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	For AE Exacerbation of hypertension: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-23-2020 13:18:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Response satisfies query
Sep-23-2020 09:31:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO Did this serious event require or prolong hospitalization?  YES Did this serious event result in persistent or significant disability/incapacity?  NO Is this serious event life threatening?  NO	Transcription Error

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1251) Achieve Clinical Research

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			Other medically important serious event  NO	
Sep-23-2020 09:29:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Exacerbation of hypertension: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate.
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			NO	
			Is this serious event life threatening ?	
			NO	
			Other medically important serious event	
			NO	

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  environmental factors, psychiatric factors	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-23-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-24-2020 04:21:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2020361606	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Medication Error (Type of Medication Error):**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Start Date:**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Is the medication error still ongoing?**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Was a Non-Drug Treatment given?**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Did the Medication Error cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Was this medication error associated with any adverse events?**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**10. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Sep-23-2020 09:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Sep-23-2020 09:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Dose Unit:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1251

Site Name: (1251) Achieve Clinical Research

Subject No: 12511050

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)				
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7. Dose Frequency:

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Sep-23-2020 09:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Visit: Logs - Unscheduled

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Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Sep-23-2020 09:33:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Transfusion Type:**

Date	Location	User	Value	Reason
Sep-23-2020 09:34:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Date of Transfusion:**

Date	Location	User	Value	Reason
Sep-23-2020 09:34:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-08-2021 14:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1251

**Site Name:** (1251) Achieve Clinical Research

**Subject No:** 12511050

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Mar-08-2021 14:22:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is NOT willing to return for Vaccination 3 OR otherwise not eligibl e	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1251

Subject No: 12511050

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1251) Achieve Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-06-2020 08:58:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Nov-04-2020 08:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Changed Information
Oct-30-2020 16:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Aug-25-2020 10:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 10:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-06-2020 08:58:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/3/2020	Changed Information
Nov-04-2020 08:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/3/2020	Changed Information
Nov-04-2020 08:18:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/3/2020	Initial Entry
Nov-04-2020 08:17:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Changed Information
Oct-30-2020 16:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/6/2020	Initial Entry
Oct-30-2020 16:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Transcription Error

090177e196ae3d0c\Final\Final On: 01-Apr-2021 04:24 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Aug-25-2020 10:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Initial Entry
Aug-25-2020 10:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/25/2020	Initial Entry



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1251

**Subject No:** 12511050

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1251) Achieve Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-09-2020 08:28:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry